

## PATENT COOPERATION TREATY

PCT

From the INTERNATIONAL BUREAU

NOTIFICATION OF THE RECORDING  
OF A CHANGE(PCT Rule 92bis.1 and  
Administrative Instructions, Section 422)

To:

AWAPATENT AB  
Box 11394  
S-404 28 Göteborg  
SUÈDE

Date of mailing (day/month/year)

17 September 2001 (17.09.01)

Applicant's or agent's file reference

2006833

## IMPORTANT NOTIFICATION

International application No.

PCT/SE00/01871

International filing date (day/month/year)

28 September 2000 (28.09.00)

## 1. The following indications appeared on record concerning:

☒ the applicant ☐ the inventor ☐ the agent ☐ the common representative

Name and Address

ASTRAZENECA AB  
S-151 85 Södertälje  
Sweden

State of Nationality

SE

State of Residence

SE

Telephone No.

Facsimile No.

Teleprinter No.

## 2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☒ the person ☐ the name ☐ the address ☐ the nationality ☐ the residence

Name and Address

ASTRA TECH AB  
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S-431 21 Mölndal  
Sweden

State of Nationality

SE

State of Residence

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Facsimile No.

Teleprinter No.

## 3. Further observations, if necessary:

## 4. A copy of this notification has been sent to:

☒ the receiving Office ☐ the designated Offices concerned  
☐ the International Searching Authority ☒ the elected Offices concerned  
☒ the International Preliminary Examining Authority ☐ other:The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Authorized officer

François BAECHLER

Facsimile No.: (41-22) 740.14.35

Telephone No.: (41-22) 338.83.38

## PATENT COOPERATION TREATY

## PCT

## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner  
 US Department of Commerce  
 United States Patent and Trademark  
 Office, PCT  
 2011 South Clark Place Room  
 CP2/5C24  
 Arlington, VA 22202  
 ETATS-UNIS D'AMERIQUE  
 in its capacity as elected Office

<b>Date of mailing</b> (day/month/year) 12 July 2001 (12.07.01)	
<b>International application No.</b> PCT/SE00/01871	<b>Applicant's or agent's file reference</b> 2006833
<b>International filing date</b> (day/month/year) 28 September 2000 (28.09.00)	<b>Priority date</b> (day/month/year) 06 October 1999 (06.10.99)
<b>Applicant</b> NESTENBORG, Daniel	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:  
 12 April 2001 (12.04.01)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was  
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

<b>The International Bureau of WIPO</b> 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No.: (41-22) 740.14.35	Authorized officer  Charlotte ENGER  Telephone No.: (41-22) 338.83.38
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# TENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 2006833	<b>FOR FURTHER ACTION</b>	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/SE00/01871	International filing date (day/month/year) 28.09.2000	Priority date (day/month/year) 06.10.1999
International Patent Classification (IPC) or national classification and IPC <sub>7</sub> A61F 5/44, A61M 25/00		
Applicant  AstraZeneca AB et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.  
  
☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of \_\_\_\_\_ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand  12.04.2001	Date of completion of this report  10.01.2002
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. 08-667 72 88	Authorized officer  Leif Brander/EK Telephone No. 08-782 25 00

**I. Basis of the report****1. With regard to the elements of the international application:\***

- ☒ the international application as originally filed
- ☐ the description:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the claims:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, as amended (together with any statement) under article 19  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the drawings:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the sequence listing part of the description:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

**2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.**

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

**3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:**

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

**4. ☐ The amendments have resulted in the cancellation of:**

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheet/fig \_\_\_\_\_

**5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2 (c)).\*\***

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item I and annexed to this report.

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE00/01871

## III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 28

because:

☒ the said international application, or the said claims Nos. 28

relate to the following subject matter which does not require an international preliminary examination (*specify*):

Method for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods (PCT Rule 67.1(iv)).

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_ are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. \_\_\_\_\_

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE00/01871

## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. Statement

Novelty (N)	Claims	<u>1-27</u>	YES
	Claims		NO
Inventive step (IS)	Claims	<u>1-27</u>	YES
	Claims		NO
Industrial applicability (IA)	Claims	<u>1-27</u>	YES
	Claims		NO

### 2. Citations and explanations (Rule 70.7)

Documents cited in the International Search Report:

1. WO 9930652 A1
2. DE 4436796 A1
3. GB 2251384 A
4. US 4325370 A
5. US 5217439 A

The cited documents represent the general state of the art.

The invention defined in claims 1-27 is not disclosed by any of these documents.

The cited prior art does not give any indication that would lead a person skilled in the art to the claimed rectal insertion device having a first and a second passageway. Therefore, the claimed invention is not obvious to a person skilled in the art.

According to the arguments stated above, the invention claimed in claims 1-27 is novel, considered to involve an inventive step and have industrial applicability.

REC'D 23 JAN 2002

WIPO

PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 2006833	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/SE00/01871	International filing date (day/month/year) 28.09.2000	Priority date (day/month/year) 06.10.1999
International Patent Classification (IPC) or national classification and IPC <sub>7</sub> A61F 5/44, A61M 25/00		
Applicant  AstraZeneca AB et al		

<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of _____ sheets.</p>
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>

Date of submission of the demand  12.04.2001	Date of completion of this report  10.01.2002
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. 08-667 72 88	Authorized officer  Leif Brander/EK Telephone No. 08-782 25 00

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

E SE00/01871

**I. Basis of the report****1. With regard to the elements of the international application:\***

- ☒ the international application as originally filed
- ☐ the description:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the claims:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, as amended (together with any statement) under article 19  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the drawings:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the sequence listing part of the description:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

**2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.**

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- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

**4. ☐ The amendments have resulted in the cancellation of:**

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheet/fig \_\_\_\_\_

**5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2 (c)).\*\***

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item I and annexed to this report.



**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 28

because:

☒ the said international application, or the said claims Nos. 28

relate to the following subject matter which does not require an international preliminary examination (*specify*):

Method for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods (PCT Rule 67.1(iv)).

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_  
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported  
by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. \_\_\_\_\_

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

P SE00/01871

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims	<u>1-27</u>	YES
	Claims		NO
Inventive step (IS)	Claims	<u>1-27</u>	YES
	Claims		NO
Industrial applicability (IA)	Claims	<u>1-27</u>	YES
	Claims		NO

**2. Citations and explanations (Rule 70.7)**

Documents cited in the International Search Report:

1. WO 9930652 A1
2. DE 4436796 A1
3. GB 2251384 A
4. US 4325370 A
5. US 5217439 A

The cited documents represent the general state of the art.

The invention defined in claims 1-27 is not disclosed by any of these documents.

The cited prior art does not give any indication that would lead a person skilled in the art to the claimed rectal insertion device having a first and a second passageway. Therefore, the claimed invention is not obvious to a person skilled in the art.

According to the arguments stated above, the invention claimed in claims 1-27 is novel, considered to involve an inventive step and have industrial applicability.

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
12 April 2001 (12.04.2001)

PCT

(10) International Publication Number  
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(51) International Patent Classification<sup>7</sup>: A61F 5/44,  
A61M 25/00

(21) International Application Number: PCT/SE00/01871

(22) International Filing Date:  
28 September 2000 (28.09.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
9903613-9 6 October 1999 (06.10.1999) SE

(71) Applicant (for all designated States except US): AS-  
TRAZENECA AB [SE/SE]; S-151 85 Södertälje (SE).

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borg (SE).

(81) Designated States (*national*): AE, AG, AL, AM, AT, AT  
(utility model), AU, AZ, BA, BB, BG, BR, BY, BZ, CA,  
CH, CN, CR, CU, CZ, CZ (utility model), DE, DE (utility  
model), DK, DK (utility model), DM, DZ, EE, EE (utility  
model), ES, FI, FI (utility model), GB, GD, GE, GH, GM,  
HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KR (utility  
model), KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG,  
MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD,  
SE, SG, SI, SK, SK (utility model), SL, TJ, TM, TR, TT,  
TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

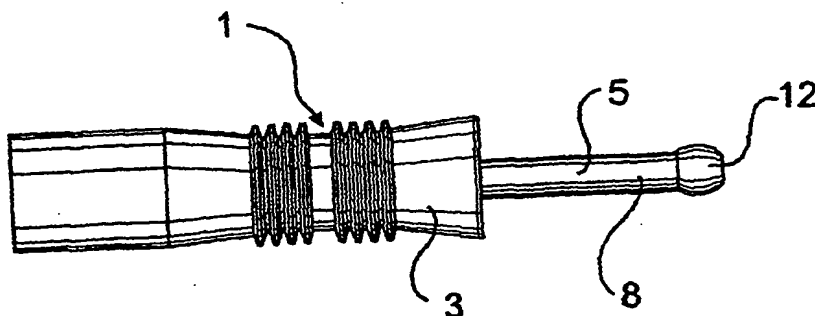
(84) Designated States (*regional*): ARIPO patent (GH, GM,  
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian  
patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European  
patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE,  
IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG,  
CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

**Published:**

- With international search report.
- Before the expiration of the time limit for amending the  
claims and to be republished in the event of receipt of  
amendments.

For two-letter codes and other abbreviations, refer to the "Guid-  
ance Notes on Codes and Abbreviations" appearing at the begin-  
ning of each regular issue of the PCT Gazette.

(54) Title: RECTAL INSERTION DEVICE



(57) Abstract: A rectal insertion device (1) for the treatment of disorders of the digestive tract of a human or animal patient having a body (3, 5) comprises a forward section (8) which in an operative position of the device is disposed in the anal canal of the patient, a first passageway (9) which extends rearwardly in the device from a first forward opening (11) in the forward section, a rearward section (3) having a forward end which in the operative position is disposed extra-corporeally

and a second passageway (4) which extends rearwardly in the device from a second forward opening (7) in the forward end of the rearward section. The second passageway acts to catch faeces discharged from the anal canal not caught in the first passageway.

WO 01/24743 A1

RECTAL INSERTION DEVICEField of the Invention

The present invention relates to a rectal insertion device for the treatment of disorders of the digestive tract of a human or animal patient, said device  
5 comprising a forward section which in an operative position of the device is disposed in the anal canal of the patient and a first passageway which extends rearwardly in the device from a first forward opening in the forward section. The invention further relates to a  
10 method for treatment of disorders of the digestive tract of a human or animal patient.

Disorders of the digestive tract which may be treated with rectal insertion devices of the type defined are colic, including infantile colic, haemorrhoids,  
15 constipation, gas and piles.

Background and summary of the Invention

WO 99/30652 by the same applicant discloses a rectal insertion device of the above-mentioned type, wherein the  
20 first passageway is provided to channel faeces and gastrointestinal gases released on insertion of the forward section into the anal canal into a collection bag. A drawback of this known device is that some of the released faeces, however, may be ejected over the outer  
25 surface of the forward section instead of through the first passageway and thus not be collected in the bag. This also renders the device difficult to use efficiently.

Many of the known devices for treating disorders of  
30 the digestive tract are also difficult and expensive to produce. Further, they could also be dangerous to use, since a too deep insertion into the anal canal could result in severe injuries to the intestine. This risk is especially high when treating infants.

The aim of the present invention is to provide a rectal insertion device of the above-mentioned type which alleviates at least some of the drawbacks of the prior art devices.

5       According to a first aspect of the present invention there is provided a rectal insertion device of the above-mentioned type in which there is provided a rearward section having a forward end which in the operative position is disposed extra-corporeally and a second  
10       passageway which extends rearwardly in the device from a second forward opening in the forward end of the rearward section. The second passageway acts to catch faeces discharged from the anal canal not caught in the first passageway.

15       According to a second aspect of the invention there is provided a rectal insertion device of the above-mentioned type in which there is provided a rearward section having a forward end presenting a second forward opening intended to be extra-corporeally in use, said  
20       second forward opening being arranged rearwardly from the first forward opening. The rearward section preferably comprises a rearwardly extending, second passageway being connected to the second opening.

      The device according to the invention is easy to use  
25       and produce. Further, it comprises means for collecting the released faeces ejected over the outer surface of the forward section instead of through the first passageway.

      In an embodiment of the invention the forward end of the rearward section abuts with the anus of the patient  
30       in an operative position of the device. Further it is preferred that the forward end of the rearward section has a transverse dimension greater than the transverse dimension of the forward section and the forward section extends forwardly from the forward end of the rearward  
35       section. Hereby, the depth of insertion could be precisely controlled, enabling the sphincter muscles to be stimulated if need be and gastrointestinal gases and

faeces to be discharged. The abutment also sees to that a too deep insertion of the forward section into the anal canal is avoided. Hereby, the device could be used without the risk of causing any harmful injuries to the user.

In an embodiment of the invention the forward section and rearward sections are co-axially arranged. It is also preferred that second forward opening is an annulus formed around the forward section. Hereby, the device need not have a specific rotational position in use, which makes the device self-explanatory and easier to use.

In an embodiment of the invention the first passageway communicates with the second passageway. Hereby, discharged faeces and gases will be brought together, and could thereafter emanate from the same output opening, making it easier to take care of.

In an embodiment of the invention the second passageway has a rearward opening in the rearward section.

In an embodiment of the invention the rearward section of the device comprises a tube element having an open-ended axial lumen.

In an embodiment of the invention the device comprises an elongate shaft having a forward portion which presents the forward section of the device and a rearward portion which extends rearwardly from the forward portion into the lumen of the tube element and through which the first passageway extends

In an embodiment of the invention the first passageway has a rearward opening in the rearward portion of the elongate shaft.

In an embodiment of the invention the rearward portion of the elongate shaft is spaced from, and attached to, the wall of the lumen through one or more ribs.

In an embodiment of the invention the forward section is made more flexible than the rearward section in order to form a non-harmful and convenient insertion section, while the more rigid rearward section may form a convenient gripping section.

The invention also relates to a method for treating disorders of the digestive tract of a human or animal patient, comprising the step of at least one time inserting a forward section of a device into the anal canal of the patient, said forward section comprising a first passageway which extends rearwardly in the device from a first forward opening in the forward section characterised in that the device is inserted into the anal canal into a position where a rearward section of the device abuts the anus with a forward end, said rearward section comprising a second passageway which extends rearwardly in the device from a second forward opening in the forward end of the rearward section.

Other benefits and advantageous features of the invention will be apparent from the following description and claims.

An exemplary embodiment of the invention will now be described with reference to the accompanying Figures of drawings.

25

#### Brief Description of the Drawings

Figure 1 is a side view of a rectal insertion device in accordance with a first embodiment of the invention.

Figure 2a is a cross-sectional side view of the rectal insertion device of Figure 1.

Figure 2b is an elevated view of the rectal insertion device in Figure 1.

Figure 3 is a perspective view of the rectal insertion device of Figure 1.

Figure 4 is a cross-sectional side view of a rectal insertion device according to a second embodiment of the invention.

Figure 5 is an elevated view of the rectal insertion device of Figure 4.

Figure 6 is an elevated view of a rectal insertion device according to a third embodiment of the invention.

5 Figure 7 is an elevated view of a rectal insertion device according to a fourth embodiment of the invention.

#### Description of preferred embodiments

10 In the Figures 1-3 of drawings there is shown a rectal insertion device 1 for treating disorders of the digestive tract of a human patient such as colic in accordance with a first embodiment of the invention. In the Figures 4-7 alternative embodiments are illustrated. However, someone skilled in the art would appreciate that  
15 the features of the different embodiments may be combined in different ways, and when nothing else is stated different aspects of certain features are regarded as mutually exchangeable.

The device is preferably injection moulded from a  
20 polyether block amide, such as Pebax™ (Elf Atochem).

The device 1 has a body 3,5 comprising a rearward section comprising a tube element 3 having a second passageway, preferably comprising an open-ended axial lumen 4, and an elongate shaft 5 which is mounted in the  
25 lumen 4, preferably co-axially. In a preferred embodiment the shaft is connected to the tube element through rib elements 6 so as to define an annulus 7 between the elongate shaft 5 and the lumen wall.

In the illustrated embodiments of the invention, the  
30 lumen 4 of the tube 3 ends axially in the rearward end. However, it is also conceivable to have a rearward opening debouching radially, or at least partly in a radial direction. To this end, one or several lateral openings could be arranged on the walls of the rearward  
35 section, ahead of a preferably sealed rearward end. It is also conceivable to let the tube be curved, in which case the rearward opening debouches axially, but not



rearwardly. By providing an output opening for discharged faeces and gases not debouching rearwardly, it is avoided that discharge products are ejected onto the person manoeuvring the device.

5       The tube element is preferably substantially circular in cross-section, as is illustrated in the embodiments according to Figure 1-6. However, other shapes are also conceivable, e.g. oval, such as elliptic or eye-shaped, as is illustrated by the embodiment  
10       according to Figure 7. Such a shape makes the device easier to bring into abutment with the anus of the patient.

      In Figures 1-3 the connection between the shaft 5 and the tube element 3 comprises two axially elongated  
15       rib elements 6. However, it is also possible to use one single rib element instead, or to use three or more rib elements, as is the case in the embodiment illustrated in Figures 4 and 5. Other alternative ways of obtaining such a connection are also possible. For example, the shaft 5  
20       may be radially displaced relative to the tube element 3, whereby it could be directly connected to the inner wall of the tube element, as illustrated in Figure 6. Further, the ribs need not be axially elongated, but could instead be arranged axially displaced.

25       As can be seen, the elongate shaft 5 is divided into a rearward portion which is disposed inside the lumen 4 of the tube element 3 and a forward portion 8 which protrudes from the lumen 4. The elongate shaft 5 comprises a first passageway, in this embodiment a  
30       channel 9, which extends axially therethrough from a forward opening 11 in a forward end 12 of the shaft 5 to a rearward opening 13 in a rearward end of the shaft 5. Hereby, the first passageway 8 in the forward section 5 communicates with the second passageway 4 in the rearward  
35       section 3. However, other ways of obtaining such a communication are possible. The first passageway, instead of or in addition to having a rearward opening debouching

axially inside the second passageway, could have a lateral opening arranged inside the second passageway ahead of the rearward end, and hence debouching radially, or at least partly in a radial direction.

- 5           The forward portion 8 of the elongate shaft 5 is adapted for insertion into the anal canal of the patient, as will hereinafter be described. To this end, the forward portion of the shaft 5 is preferably provided with a coating which exhibits a reduced friction in use.
- 10       Most preferably a coating which exhibits a reduced friction when wetted is used, e.g. the hydrophilic coating disclosed in EP-0 093 093 and EP-0 217 771 by the same applicant.

- Further, it is preferred that the forward end 12 of
- 15       the shaft 5 is enlarged. Hereby, a more efficient stimulation of the sphincter muscle is obtained when the forward section is introduced into the anal canal of the patient. The enlarged forward end preferably has a length in the range of 3-8 mm, and most preferably around 5 mm.
- 20       These lengths are especially suitable when the device is intended for infants. For adults a suitable length could be in the range 12-20 mm, and preferably around 15 mm. Still further, it is preferred that the enlarged end constitutes a smooth transition to the shaft 5, and
- 25       further presents a rounded forward end, in order to avoid discomfort for the user, and alleviate the risk of causing any harmful injuries.

- Further, it is preferred that the first passageway is tapering towards the forward end of the forward
- 30       section in the vicinity of the forward opening, making the forward opening the narrowest part of the first passageway. This contributes in alleviating the risk of causing injuries to the patient. Further, the risk of faeces clogging and blocking the passageway is
- 35       diminished.

          To this end, it is also advantageous to let the whole, or at least a substantial part of the first

passageway be slightly tapering in the length direction towards the front end. Such an embodiment is illustrated in the Figures 4 and 5 in the drawings. Preferably the tapering is more accentuated adjacent to the forward opening, and less accentuated in the rest of the passageway. The whole or part of the external surface of the forward portion of the forward section may also be tapering towards the forward end.

Arranged on a mid-section of the outer surface of the tube element 3 is preferably a series of circumferential ribs 15 to assist an operator in gripping the device 1. To this end, it is also advantageous to let the rearward section be at least slightly tapering towards the mid-section.

In use of the device 1, the operator inserts the enlarged forward end 12 of the elongate shaft 5 into the anal canal of the patient until the tube element 3 abuts the anus. This is the operative position of the device 1. The abutment of the tube element 3 with the anus allows the length of the forward portion 8 of the elongate shaft 5 to be correct for the patient being treated, that is, so that the enlarged forward end 12 of the shaft 5 is positioned just past the external sphincter muscles at the entry point of the anal canal thereby enabling the sphincter muscles to be stimulated if need be and gastrointestinal gases and faeces to be discharged. With this in mind, the length of the forward portion 8 of the shaft 5, i.e. the length of the part protruding from the forward end of the rearward section, should for adults be at least 30 mm, and preferably in the range 40-50 mm, and most preferably around 45 mm. The same length for infants should be in the range of about 15-35 mm, and preferably in the range 20-30, and most preferably around 25 mm. The abutment also sees to that a too deep insertion of the forward section into the anal canal is avoided. Hereby, the device could be used without the risk of causing any harmful injuries to the user.

In an alternative embodiment (not shown) the length of the forward portion may be variable. Hereby, the length of the protruding part of the device could be adjusted to suit the intended user. For example this may  
5 be obtained by arranging the elongated shaft axially displaceably relative the rearward section. Alternatively, the rearward section may be extendable, making the forward end of the rearward section displaceable relative to the forward section.

10 It is also preferred that the forward section, or the elongate shaft 5, is more flexible than the rearward section, or the tube element 3. Hereby, the rearward section provides a good grip at the same time as a preferably pliable and non-harmful forward section for  
15 insertion into the anal canal is provided. This difference in flexibility could be obtained by suitable choice of dimensions and/or material thickness of the parts. However, it could also be obtained by using different materials in different parts of the device.

20 Once the device 1 is located in the operative position, the annulus 7 between the elongate shaft 5 and wall of the lumen 4 of the tube element 3 acts to channel into the lumen 4 of the tube element 3 faeces not discharged into the lumen 4 via the channel 9 in the  
25 elongate shaft 5. Further, the device preferably comprises means for collecting discharged faeces or gases. For example, a bag (not shown) secured to the tube element 3 as in WO99/30652 *supra* could be arranged to collect the faeces and gases discharged into the lumen 4  
30 through the channel 9 and annulus 7. Alternately, the tube element 3 could have a sealed rear end so that the tube element 3 acts as a container for the faeces and gases. It is also conceivable to connect the discharge output to some type of per se known suction or evacuation  
35 device.

It will be understood that the invention has been illustrated by an exemplary embodiment and that the

invention can be varied in many ways within the ambit of the appended claims. For instance, the rectal insertion device can be made from many other plastic materials besides Pebax™. It will further be understood that the  
5 inclusion in the claims of reference numerals from the Figures of drawings is for illustration and not to be construed as having a limiting effect on the claims.

CLAIMS

1. A rectal insertion device (1) for the treatment of disorders of the digestive tract of a human or animal patient comprising a forward section (8) which in an operative position of the device is disposed in the anal canal of the patient and a first passageway (9) which extends rearwardly in the device from a first forward opening (11) in the forward section characterised in that the device further comprises a rearward section (3) having a forward end which in the operative position is disposed extra-corporeally and a second passageway (4) which extends rearwardly in the device from a second forward opening (7) in the forward end of the rearward section.

2. A rectal insertion device (1) for the treatment of disorders of the digestive tract of a human or animal patient, said device comprising a forward section (8) which is intended to be inserted into the anal canal of the patient and a first passageway (9) which extends in the device from a first forward opening (11) in the forward section characterised in that it further comprises a rearward section (3), having a forward end presenting a second forward opening (7) intended to be extra-corporeally in use, said second forward opening (7) being arranged rearwardly from the first forward opening (11).

3. A rectal insertion device as claimed in claim 2, wherein the rearward section (3) comprises a, preferably rearwardly extending, second passageway (4) being connected to the second opening (7).

4. A rectal insertion device as claimed in claim 1, 2 or 3, wherein in an operative position of the device the forward end of the rearward section (3) abuts with the anus of the patient.

5. A rectal insertion device as claimed in claim 1 or 3, wherein the first and second passageways (9, 4) are substantially co-axially arranged.

6. A rectal insertion device as claimed in any one  
5 of claims 1 to 5, wherein the forward end of the rearward section (3) has a transverse dimension greater than the transverse dimension of the forward section (8), the forward section (8) extending forwardly from the forward end of the rearward section (3).

10 7. A rectal insertion device as claimed in any one of claims 1 to 6, wherein the forward section (8) and rearward section (3) are co-axially arranged.

8. A rectal insertion device as claimed in any one of claims 1 to 6, wherein the forward section (8) is  
15 arranged parallel but radially displaced relative to the rearward section (3).

9. A rectal insertion device as claimed in claim 6, 7 or 8, wherein the second forward opening (7) is in the form of an annular opening formed around the forward  
20 section (8).

10. A rectal insertion device as claimed in claim 1 or 3, wherein the first passageway (9) communicates with the second passageway (4).

11. A rectal insertion device as claimed in claim  
25 10, wherein the first passageway (9) has a rearward opening debouching inside the second passageway (4).

12. A rectal insertion device as claimed in any one of claims 1 to 11, wherein the rearward section (3) of the device comprises a tubular element (3), preferably  
30 having an open-ended axial lumen.

13. A rectal insertion device as claimed in claim 12, wherein the device comprises an elongate shaft (5) having a forward portion (8) which presents the forward section of the device and a rearward portion which  
35 extends rearwardly from the forward portion into the tubular element (3).

14. A rectal insertion device as claimed in claim 13, wherein the first passageway (9) extends through essentially the whole elongate shaft (5).

5 15. A rectal insertion device as claimed in claim 14, wherein the first passageway (9) has a rearward opening (13) in the rearward portion of the elongate shaft (5).

10 16. A rectal insertion device as claimed in any one of claims 13 to 15, wherein the rearward portion of the elongate shaft (5) is spaced from the inner wall of the tubular element (3).

15 17. A rectal insertion device as claimed in claim 16, wherein the elongate shaft (5) is attached to the inner wall of the tubular element (3) through one or more rib elements (6).

18. A rectal insertion device as claimed in any one of the preceding claims, wherein the rearward section (3) comprises a gripping portion (15) for manoeuvring the device.

20 19. A rectal insertion device as claimed in any one of the preceding claims, wherein the forward section (8) is more flexible than the rearward section (3).

25 20. A rectal insertion device intended for adults as claimed in any one of the preceding claims, wherein the length of the forward section (8) protruding from the forward end of the rearward section (3) is at least 30 mm, and preferably in the range 40-50 mm, and most preferably around 45 mm.

30 21. A rectal insertion device intended for infants as claimed in any one of claims 1 to 19, wherein the length of the forward section (8) protruding from the forward end of the rearward section (3) is in the range of about 15-35 mm, and preferably in the range 20-30, and most preferably around 25 mm.

35 22. A rectal insertion device as claimed in any one of the preceding claims, wherein the device further comprises means for collecting faeces discharged into at



least one, and preferably both, of the first and second forward openings.

23. A rectal insertion device as claimed in claim 22, wherein the means for collecting faeces comprises a collection receptacle, and preferably a collection bag.

24. A rectal insertion device as claimed in claim 22, wherein the means for collecting faeces comprises a rearwardly sealed passageway connected to the opening.

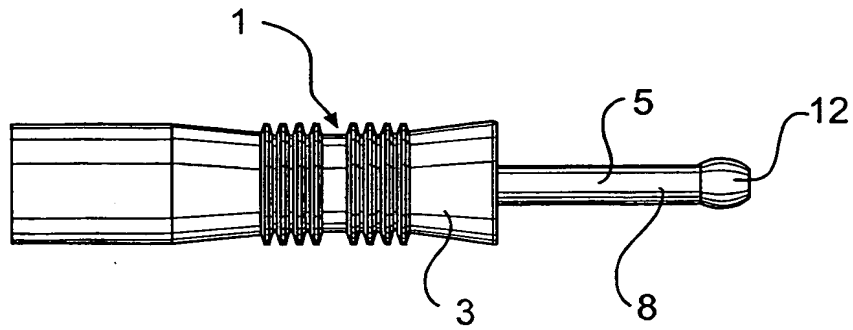
25. A rectal insertion device as claimed in any one of the preceding claims, wherein the forward section (8) presents a transversely enlarged forward end portion (12).

26. A rectal insertion device as claimed in any one of the preceding claims, wherein the first passageway (9) is tapering towards the forward end of the forward section (8), making the forward opening the narrowest part of the first passageway (9).

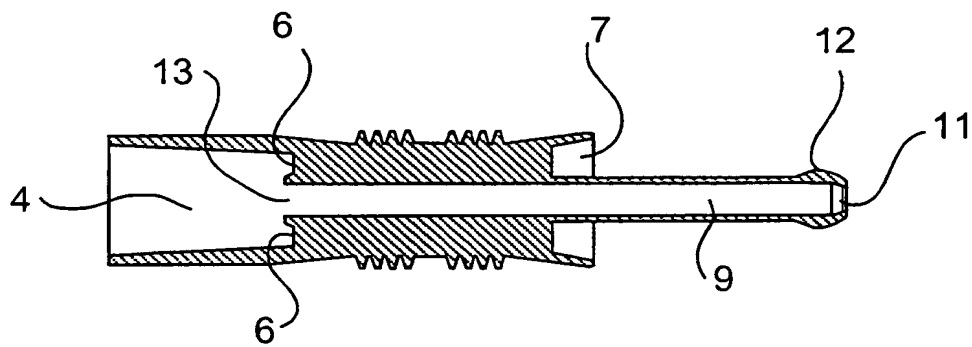
27. A rectal insertion device as claimed in any one of the preceding claims, wherein the rearward section (3) is at least slightly tapering towards a mid-section.

28. A method for treating disorders of the digestive tract of a human or animal patient, comprising the step of at least one time inserting a forward section (8) of a device into the anal canal of the patient, said forward section (8) comprising a first passageway (9) which extends rearwardly in the device from a first forward opening (11) in the forward section (8) characterised in that the device is inserted into the anal canal into a position where a rearward section (3) of the device abuts the anus with a forward end, said rearward section (3) comprising a second passageway (4) which extends rearwardly in the device from a second forward opening (7) in the forward end of the rearward section.

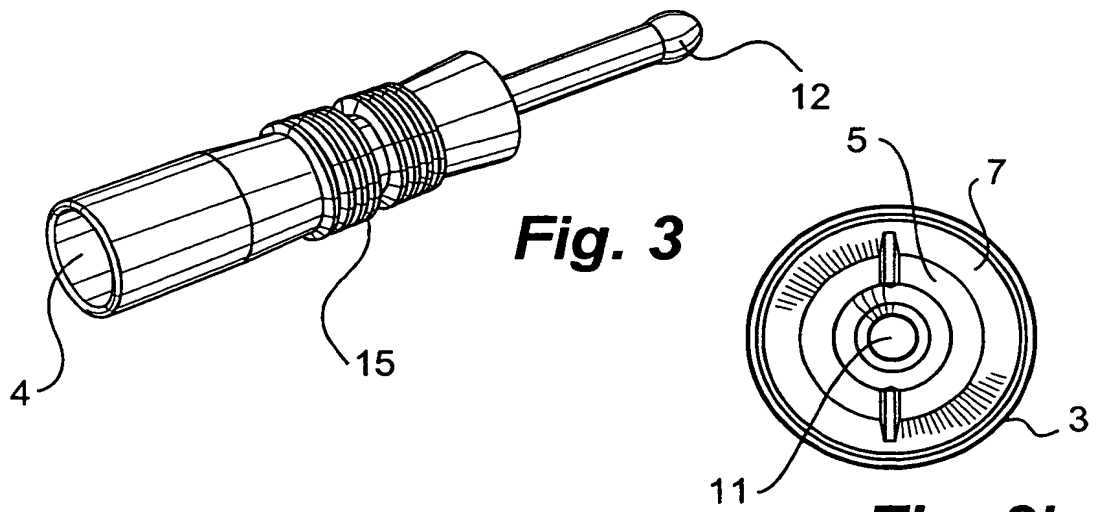
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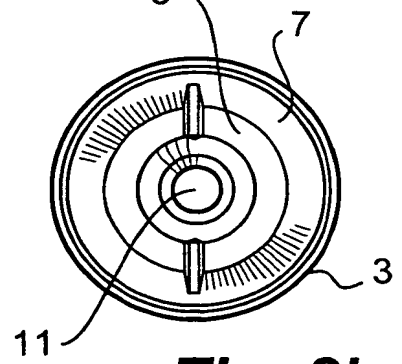
**Fig. 1**



**Fig. 2a**

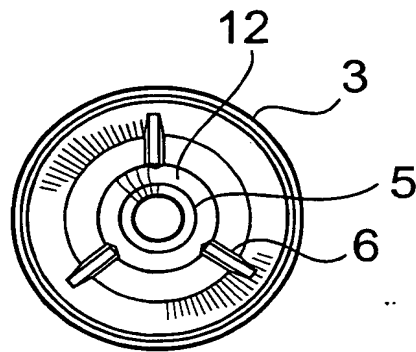


**Fig. 3**

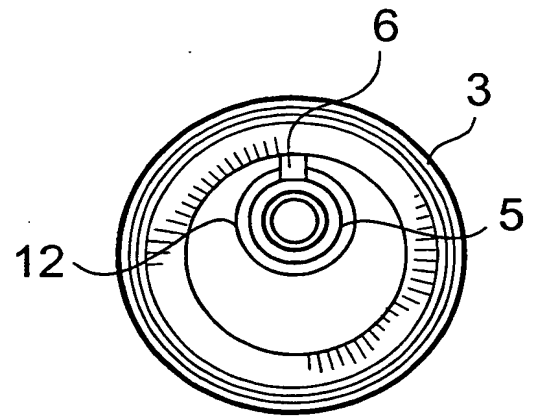


**Fig. 2b**

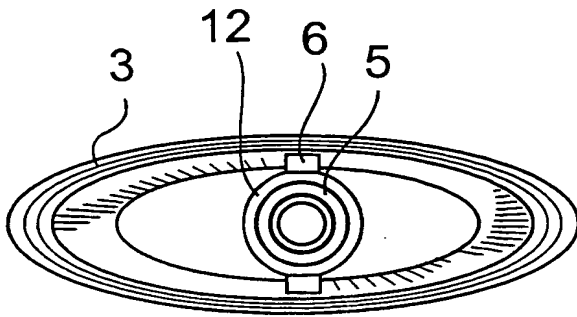
2/2



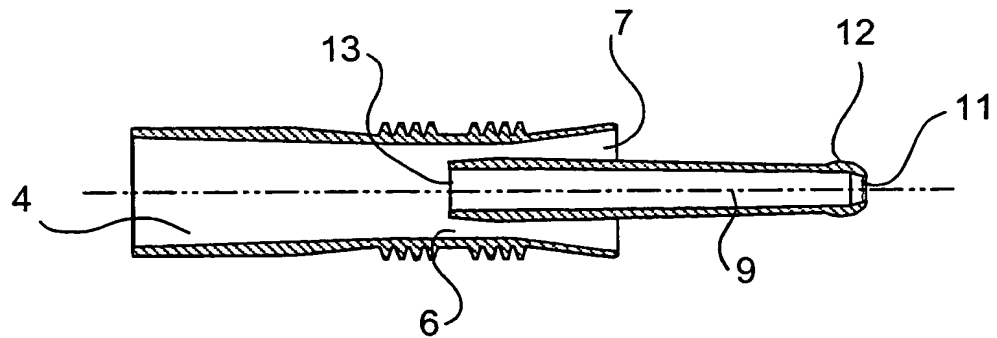
**Fig. 5**



**Fig. 6**



**Fig. 7**



**Fig. 4**

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 00/01871

## A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61F 5/44, A61M 25/00

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61F, A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPODOC, MEDLINE

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 9930652 A1 (ASTRA AKTIEBOLAG), 24 June 1999 (24.06.99), figure 1, claims 1-3 --	1-27
A	DE 4436796 A1 (VIA LOG MEDIKALPRODUKTE GMBH KOSMETIK-MEDIEN), 11 April 1996 (11.04.96), figure 3A --	1-27
A	GB 2251384 A (CHRISTOPHER DANIEL DOWLING HICKEY), 8 July 1992 (08.07.92), figures 1-2, abstract --	1-27
A	US 4325370 A (YOUNG), 20 April 1982 (20.04.82), figures 1-2, abstract --	1-27

☒ Further documents are listed in the continuation of Box C.☒ See patent family annex.

\* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&amp;" document member of the same patent family

Date of the actual completion of the international search

31 January 2001

Date of mailing of the international search report

05-02-2001

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## INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 00/01871

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5217439 A (MCCLUSKY), 8 June 1993 (08.06.93), figures 1-2, abstract  -- -----	1-27

# INTERNATIONAL SEARCH REPORT

International application No.  
**PCT/SE00/01871**

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: **28**  
because they relate to subject matter not required to be searched by this Authority, namely:  
**Method for treatment of the human or animal body by surgery or therapy as well as diagnostic methods (PCT Rule 3.9.1(iv)).**
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.  
☐ No protest accompanied the payment of additional search fees.

**INTERNATIONAL SEARCH REPORT**  
Information on patent family members

27/12/00

International application No.

PCT/SE 00/01871

Patent document cited in search report			Publication date	Patent family member(s)	Publication date
WO	9930652	A1	24/06/99	AU 1898799 A BR 9813580 A EP 1039858 A NO 20003052 A SE 9704712 D	05/07/99 17/10/00 04/10/00 14/06/00 00/00/00
DE	4436796	A1	11/04/96	NONE	
GB	2251384	A	08/07/92	DE 69115257 D EP 0511245 A,B GB 9100073 D US 5325199 A	00/00/00 04/11/92 00/00/00 28/06/94
US	4325370	A	20/04/82	NONE	
US	5217439	A	08/06/93	NONE	